

## COMMENTS

Claims 1, 6, and 11 have been amended. Claims 1-14 are all the claims in the case.

### Rejections under 35 USC § 102

The examiner rejected claims 1-4, 6-9, 11-14 under 35 USC § 102(b) as anticipated by US Patent 5,411,484 to Shattuck. This rejection is traversed.

Applicants have amended claims 1, 6, and 11 to recite a circular one-piece fabric band which is divided into closed loops. This recitation is supported in the specification at page 2, line 20; page 3, lines 8-15; and Fig. 3.

The Shattuck patent does not teach or disclose a circular band divided into closed loops. Instead, the Shattuck patent discloses a strap, which is not circular. The ends of the strap are equipped with velcro so that, when the strap is placed around the head, the left end can be looped around a mouth tube and the right end can be looped around the mouth tube, and thus hold the tube in place by the exertion of directionally opposing forces. The ends do not meet and therefore do not form a circular band even when the device is fully in place. See Figs. 4 and 5. Because there is no circular band, there is no circular band is divided into closed loops. Since these claim limitations are not taught or disclosed in the Shattuck patent, the rejected claims are not anticipated by the Shattuck patent.

The examiner also rejected claims 1-4, 6-9, and 11-14 under § 102(b) as anticipated by US Patent 4,723,325 to Perry. This rejection is traversed.

The rejected claims recite that the closed loops are capable of receiving and holding medical tubing close to the body. The Perry patent, on the other hand, discloses a length of fabric configured to form one loop which encircles the head and a larger loop which drapes around the user's neck, shoulder and upper chest for use as a facial wipe. There is no disclosure of a loop fitting tight to the head so as to hold medical tubing close to the head. In fact, Perry teaches against such a tight fitting loop since the purpose of the extra loop is to provide a towel substitute, which by necessity needs to be long and loose. Thus Perry does not teach or disclose a device having all the limitations of the rejected claims. Withdrawal of this rejection is respectfully requested.

#### Rejection under 35 USC § 103

The examiner rejected claim 5 and 10 under 35 USC § 103 as obvious over the Shattuck patent and in further view of US Patent 3,878,849 to Muller. This rejection is traversed.

As pointed out *supra*, the Shattuck patent does not teach or disclose a circular band which is divided into closed loops, which are limitations of claims 1 and 6 from which claims 5 and 10 depend.

The Muller patent discloses a strap having a loop attached thereto for holding tubing close to the body. It does not, however, teach or disclose a circular band divided into closed loops, and thus does not suggest, alone or in combination with the Shattuck

patent, the claims of the present invention.

Further, as pointed out in the declaration of Terri Lee Maurer, submitted herewith, the Shattuck patent does not suggest or disclose to one skilled in the art a device that would be appropriate for tube-administered therapy. See Maurer Decl. ¶ 11.

As discussed in the Maurer declaration, the problems with the device disclosed in the Shattuck patent are manifold. Since therapy such as CPAP requires that two prongs be used, one for each nostril, one would need two Shattuck straps, thus doubling the possibility of skin irritation caused by the straps. Second, the fact that the Shattuck device is tightened around the neck counteracts any inclination to attempt its use for infants since it is generally not considered safe to tighten straps around infants' necks. Third, the velcro on the ends of the Shattuck straps pose a source of irritation. Finally, should the velcro attachment become disconnected, the nasal prongs would shift from an effective position, thus defeating the therapy. Maurer Decl. ¶ 11.

The device of the present invention, on the other hand, differs from the Shattuck teaching in that (1) only one device is needed to keep both nasal prongs in place; (2) it goes around the sturdy skull, not the vulnerable neck; (3) it has no sharp or rough portions which can irritate the skin; and (4) the loops are closed and cannot open, so the tubing cannot fall away from the body. Maurer Decl. ¶ 12.

As further discussed by Ms. Maurer and also by Dr. Veniamin Ratner in his declaration, enclosed, the present invention avoids the problems of prior art devices and is a significant and useful development in the art of attaching tubing to a patient for effective and continuous therapeutic administration. It is not prone to slippage as are

many of the prior art devices. It is comfortable for the patient and allows patients to retain their mobility. The risk of skin irritation from attachment devices such as pins, clips, snaps, tape, or velcro is eliminated. The large surface area of the band makes it easy to manipulate around the patient's head. It adjusts easily in size to conform to a wide range of patients. In sum, the present invention is a huge non-obvious advancement over the prior art.

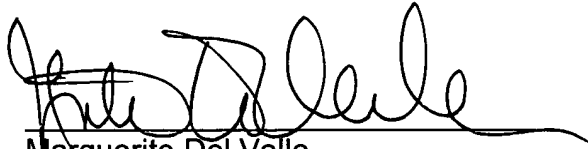
In view of the foregoing, withdrawal of the rejection based on ¶ 103 is therefore respectfully requested.

Response Pursuant to 37 CFR 1.111  
Serial No. 09/930,398  
Page 8

### CONCLUSION

In view of the foregoing, it is submitted that the claims as amended present patentable subject matter. Allowance is respectfully requested.

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A handwritten signature in black ink, appearing to read 'Marguerite Del Valle', written over a horizontal line.

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